Internal Memo
Ministry Of Health

To: [redacted] MAAC Secretary

From: Antony Fake, Team Leader Prescription Medicines

Subject: **Referral of Sativex Oral Spray (TT50-8053) to the MAAC**

Date: 27 October 2009

For Your: ACTION: √ DECISION: INFORMATION:

Dear [redacted]

The assessment of an application for provisional consent of Sativex Oral Spray by Medsafe has been completed. A definitive recommendation to the Ministry of Health to approve this product could not be made and therefore this application has been referred to the MAAC for consideration.

The application for the new medicine Sativex was made by GW Pharma on 7 January 2008. Sativex is notable in that it is the first medicine containing the active components tetrahydrocannibanol and cannibanol.

The pharmaceutical chemistry aspects of this application have been assessed and found to be acceptable.

Clinical evaluation of this application occurred in two stages. The initial clinical evaluation was undertaken by the MAAC in keeping with MAAC procedures of the time. The MAAC deferred a recommendation and requested further information. This further information was received by Medsafe on 1 December 2008. Due to a change in MAAC procedures this data did not go directly back to the MAAC for consideration. Rather, the primary and secondary evaluators assessed the further data and made their recommendations directly to Medsafe. Their reports have been reviewed. Medsafe's final clinical recommendation on this product is:

- That a recommendation to approve the indications "relief of cancer pain" and "relief of neuropathic pain" can not be made.
- That a recommendation to approve the indication "relief of spasticity in MS" may be considered under section 23, subject to MAAC endorsement.

It is clear from the evaluation reports that there is an absence of conclusive data on the efficacy of this product. However, as approval under section 23 has been requested increased importance on the relative risk:benefit profile of the product, particularly in the patient population concerned is an important consideration and MAAC members are asked to note this in their considerations.

Yours sincerely

Antony Fake

Team Leader

Prescription Medicine Evaluation